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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,457	11/02/2000	James Andya	P0998D3	7899

9157 7590 07/10/2002
GENENTECH, INC.
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/10/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/705,457

Applicant(s)
Andya et al.

Examiner
Marianne DiBrino

Art Unit
1644



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 19, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-44 is/are pending in the application
- 4a) Of the above, claim(s) 41-43 is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 4/19/02 (Paper No. 13) is acknowledged and has been entered.

Claims 37- 44 are pending.

2. Applicant is reminded that claims 37-40 and 44 are currently being examined as they read on a method for treating an IgE-mediated disease in a mammal comprising administering a formulation comprising an antibody which binds IgE.

Claims 37-40 and 44 are presently being examined.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 37-40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,709 (provide in last office action) in view of U.S. Patent No. 5,580,856 (IDS reference).

U.S. Patent No. 5,965,709 discloses allergy therapy (i.e., IgE-mediated disease) by administration of an anti-IgE antibody or anti-IgE fragments such as Fab or Fab' (especially col. 32, para 3), including by subcutaneous injection (especially col. 33, para 1) in amounts of about 2-3 mg/kg (especially column 33, para 4). U.S. Patent No. 5,965,709 further discloses pharmaceutical excipients which would serve as lyoprotectants such as mannitol, lactose, starch, magnesium carbonate, magnesium stearate, sodium saccharin and cellulose (especially col. 33, para 1).

U.S. Patent No. 5,965,709 does not teach that the reconstituted formulation comprising an anti-IgE antibody is present in an amount of about 50 mg/ml to about 400 mg/ml.

U.S. Patent No. 5,580,856 discloses a reconstituted (from lyophilized form) stable isotonic medicinal formulation used for treating disease in a warm-blooded mammal, including humans, comprising a protein, including antibodies (especially col. 6 at the last paragraph through col. 7 at line 3) in the amount of about 0.05 to about 20,000 ug/ml (i.e., the upper limit is about 20 mg/ml which meets the limitations of the instant claims "about 50 mg/ml) (especially the paragraph spanning col. 7 and col. 8). U.S. Patent No. 5,580,856 further discloses lyoprotectants such as sucrose, trehalose, histidine and succinate (especially column 1 at the last paragraph through column 2 at line 18, and col. 4 at the last paragraph through col. 5).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have reconstituted the anti-IgE antibody in the pharmaceutical composition disclosed by U.S. Patent No. 5,965,709 at the concentration disclosed for the antibody of the medicinal composition disclosed by U.S. Patent No. 5,580,856 for use in the method of treatment disclosed by U.S. Patent No. 5,965,709.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because both U.S. Patent No. 5,965,709 and U.S. Patent No. 5,580,856 disclose methods of treatment of human disease using a pharmaceutical composition comprising a reconstituted lyophilized antibody and lyoprotectant, and U.S. Patent No. 5,580,856 discloses a concentration of about 20 mg/ml for the reconstituted antibody.

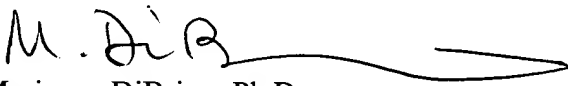
The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

5. The IDS references referred to by Applicant on page 2 at the last two paragraphs of Applicant's amendment filed 4/19/02 have not been considered because they can not be located.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



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July 9, 2002



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